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09/914,546	03/12/2002	Hiroshi Tanaka	YAM2 0010	9731

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EXAMINER

HELMER, GEORGIA L

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/914,546

Applicant(s)

TANAKA ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

### **DETAILED ACTION**

1. Claims 1-5 are pending and are examined in this action.

#### ***Information Disclosure Statement***

2. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 4, filed 17 June 2002, is attached to the instant Office action.

#### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the evidence as described in the specification. Figure 3 is of such poor quality that the Examiner is unable to evaluate the data the Figure is cited as representing. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112-second***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-5 are rejected under 35 U.S.C. 112-2<sup>nd</sup>.

In claim 1, and claims 2-5 dependent thereon,

- the word "plant" should be inserted after the word "monocotyledon", for clarity, and "monocotyledon" would be replaced with "monocotyledonous",
- "Gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired. All subsequent recitations of this language are also rejected.
- Claim 1 is an incomplete method claim because the final step of the method does not produce the desired product.
- Claim 1 is also indefinite and confusing in the recitation of "intact seed". It is unclear what is intended, particularly in view of claims 2 and 3, that include further limitations that the seed is germinated seed.

Clarification/correction is required.

***Claim Rejections - 35 USC § 112-Enablement***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification,

while being enabling for a method (specification, Example I, pages 16-19), for the transformation of a rice plant by (i) preculturing rice seeds on N6D medium containing 2,4-D and sucrose for 5 days at 27-32C (as described in Section 1.1, specification, page 16),(ii) Agrobacterium infection by immersing precultured seed in a suspension of Agrobacterium bearing pLGHm plasmid, and incubating in the dark at 28C for three days, (as described in Section 1.3, p 17), followed by elimination of Agrobacterium using carbenicillin, (as described in Section 1.4, p 17), (iii) selection (as described in Section 1.4, pages 17-18), by placing the seeds on ND6 medium containing 2, 4-D, 2 mg/liter, plus carbenicillin (500 g/l) and hygromycin (25 mg/l) and incubating at 27C for 7 more days, (iv) a second selection (as described in Section 1.4, page18), by placing the seeds on ND6 medium containing 2, 4-D, 2 —4 mg/liter, plus carbenicillin (500 g/l) and hygromycin (25 mg/l) and incubating 27C for 7 more days, (v) regenerating plants using regeneration medium as described (as described in Section 1.5, pages 18-19); is not enabling for a method of transforming any monocot comprising a step of infecting an intact seed with Agrobacterium bearing a desired DNA of interest ,where the seed is on the 4<sup>th</sup> or 5<sup>th</sup> day after sowing, where the seed is

germinated seed, where the plant is of the family Gramineae, where the plant is rice, all these being under unspecified conditions.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

*The breadth of the claims and the nature of the invention:* The claims are drawn to a method of transforming any monocot, comprising a step of infecting an intact seed with *Agrobacterium* bearing a desired DNA of interest, where the seed is on the 4<sup>th</sup> or 5<sup>th</sup> day after sowing, where the seed is germinated seed, where the plant is of the family Gramineae, where the plant is rice. Applicant's claims encompass all monocots, all monocot seeds, all *Agrobacterium*, using any and all starting materials, protocols, and conditions.

Applicant teaches a method (specification, Example I, pages 16-19), for the transformation of a rice plant by

(i) preculturing rice seeds on N6D medium containing 2,4-D and sucrose for 5 days at 27-32C (as described in Section 1.1, specification, page 16),

(ii) *Agrobacterium* infection by immersing precultured seed in a suspension of *Agrobacterium* bearing pGIHm plasmid, and incubating in the dark at 28C for three days, (as described in Section 1.3, p 17), followed by elimination of *Agrobacterium* using carbenicillin, (as described in Section 1.4, p 17),

(iii) selection (as described in Section 1.4, pages 17-18), by placing the seeds on ND6 medium containing 2, 4-D, 2 mg/liter, plus carbenicillin (500 g/l) and hygromycin (25 mg/l) and incubating at 27C for 7 more days,

(iv) a second selection (as described in Section 1.4, page18), by placing the seeds on ND6 medium containing 2, 4-D, 2 —4 mg/liter, plus carbenicillin (500 g/l) and hygromycin (25 mg/l) and incubating 27C for 7 more days,

(v) regenerating plants using regeneration medium as described (as described in Section 1.5, pages 18-19).

The recited method of claim 1, lacking a nucleotide sequence encoding a selective marker, and selection steps, is lacking essential elements. Inoculation with *Agrobacterium* followed by culturing in a medium without any selection step would not predictably produce transgenic tissue or plants. Rather, a mixed population of transformed and untransformed cells would result. Such a mixed population would require many plants to be screened in order to find the plant having the desired transgenic tissue. In the absence of selection the mixed population favoring the non-transgenic tissue would be produced. See Birch, Annu. Rev. Plant Physiol. Plant Mol. Biol. 1997, 48:297-326 especially p 302, and Figure 1, p 304. Such screening would require undue experimentation for one skilled in the art to which it pertains to make and use the claimed invention as commensurate in scope with these claims.

In view of the breadth of the claims (a method of transforming any monocot plant, using any *Agrobacterium*, and under any conditions); the nature of the invention, the

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unpredictability of the art, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



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9. Claims 1-5 are rejected under 102(b) as being anticipated by Goldman, et al, US 5,187,073, issued 16 February 1993.

Goldman teaches a method for transforming rice (column 4, line 20), comprising a step of infecting a seed on the 4<sup>th</sup> or 5<sup>th</sup> day after planting (column 8, lines 58-60), where the seed is germinated (claims 1-3) with an Agrobacterium containing a DNA of interest (col 11, lines 55-65).

Accordingly, Goldman anticipates the claimed method.

10. Claims 1 is rejected under 102(b) as being anticipated by Mahalakshmi, et. al., Plant Biochemistry and Biotechnology, Vol 4, 55-59, 1995.

Mahalakshmi teaches a method for transforming wheat (Abstract and Table 4, page 58), comprising a step of infecting an intact seed (Table 4, and 1<sup>st</sup> paragraph, page 58,) with an Agrobacterium containing a DNA of interest (p 55, 2<sup>nd</sup> column).

Accordingly Mahalakshmi anticipates the claimed method.

11. Claims 1-4 are rejected under 102(b) as being anticipated by Grimsley, pages 325-342, in Methods in Molecular Biology, Vol. 44: Agrobacterium Protocols, Editors Gartland and Davey, Humana Press, Totowa, NJ, 1995.

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Grimsley teaches a method for transforming maize (p 334, final 4 lines), comprising a step of infecting a 3-5 day old seedling, (Section 3.3, p 335) with an Agrobacterium containing a DNA of interest (Section 3.32, p 334).

Accordingly, Grimsley anticipates the claimed invention.

### Remarks

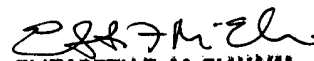
12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner  
Art Group 1638  
April 18, 2003

  
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